

### **III. Remarks**

#### **A. Status of the Application**

Claims 1 and 4-19 will be pending after entry of the present paper. Claims 1 and 3-19 were previously pending. Claim 3 is canceled by the present paper without prejudice to or disclaimer of the subject matter therein. No claims are added by the present paper. Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

#### **B. Claim Rejections Under 35 U.S.C. § 103**

##### **1. Middleton and Reiley Patents**

Claims 1, 3-7, 9-12, and 14-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,746,451 to Middleton et al. ("Middleton patent") in view of U.S. Patent No. 6,863,672 to Reiley et al. ("Reiley patent"). As noted above, claim 3 is canceled by the present paper. Accordingly, the rejection of claim 3 is moot and will not be addressed at this time.

The PTO provides in MPEP § 2131 that

"The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness."

The Examiner clearly cannot, using the Middleton and Reiley patents, establish a *prima facie* case of obviousness in connection to claim 1, 4-7, 9-12, and 14-19 for at least the following reason.

35 U.S.C. § 103(a) provides, in part, that:

"A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . ."  
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

With respect to amended independent claim 1, even when combined the Middleton and Reiley patents fail to disclose or suggest:

1. An enucleation device comprising:

a cutting cap comprising a plurality of deformable blades sized and shaped for cutting a portion of a spinal segment, the deformable blades deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another and an insertion configuration where the deformable blades extend generally parallel to one another, wherein the orthogonally-expanded cutting configuration is a neutral position for the deformable blades and the insertion configuration is a deformed position for the deformable blades such that when the deformable blades are not deformed the deformable blades return to the orthogonally-expanded cutting configuration, wherein the deformable blades are positioned radially about a central opening extending through the cutting cap to allow the cutting cap to be placed over a guidewire;

a hollow flexible shaft fixedly connected to the cutting cap, the hollow flexible shaft including an axial lumen extending along the length of the hollow flexible shaft and in communication with the central opening of the cutting cap such that the hollow flexible shaft is configured to be placed over the guidewire;

a hypotube positioned around at least a proximal portion of the hollow flexible shaft and fixedly connected to a user graspable handle of the enucleation device;

a shrink tube positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap, the shrink tube having a reduced outer diameter relative to the hypotube such that the shrink tube provides a bearing surface between the hollow flexible shaft and the hypotube; and

a motor adapter positioned adjacent to the proximal portion of the hollow flexible shaft, the motor adapter configured to connect the enucleation device to a motor drive for rotating the flexible shaft to cause rotation of the cutting cap;

where the plurality of elastically deformable blades can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed; and

where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material.

In that regard, the Middleton and Reiley patents simply do not disclose or suggest an enucleation device that includes a cutting cap, hollow flexible shaft, hypotube, user graspable handle, and shrink tube having all of the features recited in claim 1. For example, neither of the Middleton or Reiley patents discloses or suggests the combination of a cutting cap having a plurality of deformable blades positioned radially about a central opening, a hollow flexible shaft

fixedly connected to the cutting cap, a hypotube positioned around at least a proximal portion of the hollow flexible shaft and connected to a user graspable handle, and a shrink tube positioned around at least a distal portion of the hollow flexible shaft that provides a bearing surface between the hollow flexible shaft and the hypotube. Accordingly, a *prima facie* case of obviousness cannot be established with respect to independent claim 1. Claims 4-17 require the enucleation device of claim 1. Thus, Applicants request that the § 103 rejection of claims 1 and 4-17 over the Middleton and Reiley patents be withdrawn.

With respect to amended independent claim 18, even when combined the Middleton and Reiley patents fail to disclose or suggest:

18. An enucleation device comprising:

a proximal end;

a distal end comprising a cutting cap sized and shaped for cutting a portion of a spinal segment, the cutting cap comprising a plurality of deformable blades comprising a shape memory alloy, wherein the deformable blades are deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another about a central opening extending through the cutting cap to allow the cutting cap to be placed over a guidewire and an insertion configuration where the deformable blades extend generally parallel to one another and parallel to a longitudinal axis of the central opening, wherein the shape memory alloy of the deformable blades is processed such that the orthogonally-expanded cutting configuration is a neutral position for the deformable blades and the insertion configuration is a deformed position for the deformable blades such that when the deformable blades are not deformed the deformable blades return to the orthogonally-expanded cutting configuration;

a hollow flexible shaft extending between the proximal end and the cutting cap, the hollow flexible shaft fixedly attached to the cutting cap and including an axial lumen extending along the length of the hollow flexible shaft in communication with the central opening of the cutting cap such that the hollow flexible shaft is configured to be placed over the guidewire;

a hypotube positioned around at least a proximal portion of the hollow flexible shaft and fixedly connected to a user graspable handle of the enucleation device;

a shrink tube positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap, the shrink tube providing a bearing surface between the hollow flexible shaft and the hypotube; and

a motor adapter positioned adjacent to the proximal end,  
the motor adapter configured to connect the hollow flexible shaft  
to a motor drive configured to rotate the shaft to cause rotation of  
the cutting cap;

where the plurality of deformable blades can cut material in  
a space when the blades are not deformed; and

where the passage has a smaller cross-sectional area than  
the lateral cross-sectional area of the undeformed blades while the  
blades are cutting the material.

In that regard, the Middleton and Reiley patents simply do not disclose or suggest an enucleation device that includes a cutting cap, hollow flexible shaft, hypotube, user graspable handle, and shrink tube having all of the features recited in claim 18. Accordingly, a *prima facie* case of obviousness cannot be established with respect to independent claim 18. Claim 19 requires the enucleation device of claim 18. Thus, Applicants request that the § 103 rejection of claims 18 and 19 over the Middleton and Reiley patents be withdrawn.

## **2. Middleton, Reiley, and Groshong Patents**

Claims 8 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Middleton and Reiley patents in further view of U.S. Patent No. 5,178,625 to Groshong ("Groshong patent"). Claims 8 and 13 depend from and further limit claims 4 and 11, respectively, that each require the enucleation device of claim 1. As shown above, even when combined the Middleton and Reiley patents fail to disclose all of the limitations of claims 4 and 11. The Groshong patent does not affect this deficiency. Accordingly, even when combined the Middleton, Reiley, and Groshong patents fail to disclose all of the recited limitations of claims 4 and 11 and, therefore, claims 8 and 13 as well. Therefore, a *prima facie* case of obviousness cannot be established with respect to claims 8 and 13 based on the Middleton, Reiley, and Groshong patents. Thus, Applicants request that the § 103 rejection of claims 8 and 13 be withdrawn.

#### **IV. Conclusion**

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims are in condition for allowance. Accordingly, an indication of allowability is respectfully requested.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action.

Should the Examiner deem that an interview with Applicants' undersigned attorney would further prosecution, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.


Respectfully submitted,



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